Modified PTO/SB/33 (10-05)

PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number Q78108	
Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number 10/692,011	Filed October 24, 2003
	First Named Inventor Kenji NAKAJIMA	
	Art Unit 1641	Examiner Leon Yun Bon LUM

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23373
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Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal

The review is requested for the reasons(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

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April 26, 2007
Date

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q78108
Kenji NAKAJIMA, et al.	
Appln. No.: 10/692,011	Group Art Unit: 1641
Confirmation No.: 8536	Examiner: Leon Yun Bon LUM
Filed: October 24, 2003	

For: ASSAY METHOD USING A BIOCHEMICAL ANALYSIS UNIT AND BIOCHEMICAL ANALYSIS APPARATUS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the new Pre-Appeal Brief Conference Pilot Program, and further to the Examiner's Final Office Action dated October 26, 2006, Applicants file this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal.

Applicants turn now to the rejections at issue:

Claims 2-3, 5-6, 8-9, and 11-12 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hess et al (US 6,716,629 B2) in view of Clark et al (US 5,358,691).

The Examiner cites Hess as disclosing the claimed processes, except for the step of performing a bubble removing or dissolving process during the flowing of the liquid, and cites Clark as teaching a step of automatically flushing bubbles out of a fluidics system in order to prevent the presence of air bubbles from affecting the precision and accuracy of the dispenser. The Examiner asserts that the motivation to combine the references is to provide the

advantages of a more precise and accurate dispensation by removing bubbles from a fluidic system.

It is respectfully submitted that there is no motivation to combine Hess and Clark. Clark specifically discloses that the problem is associated with a syringe and discloses, at column 21, lines 7-19, that (emphasis added):

> Various elements of syringe 122 which provides automatic bubble flushing and fluids to the various pipetting mechanisms is provided in various views in FIGS. 9, 9A and 9B. The ability of diagnostic instrumentation to accurately perform an assay is ***critically dependent on the precision and accuracy with which syringes, i.e. pipetting, can aspirate and dispense reagents and samples.*** The precision and accuracy of a syringe is severely degraded by the presence of small air bubbles inside a syringe. Bubbles, unfortunately, are all too common and are difficult to remove or avoid. Syringe 122 avoids these problems by automatically flushing bubbles completely out of the fluidics system.

More importantly, Clark discloses "various elements of a syringe 122 which provides automatic bubble flushing" shown in Figures 9, 9A and 9B and various structures at column 21, lines 19-48, and discloses that "the precision and accuracy of a syringe is severely degraded by the presence of small air bubbles inside a syringe". Therefore, Clark discloses problems associated with the use of a syringe and modifications to a syringe that automatically remove bubbles formed in the syringe. The Examiner must consider the entire disclosure of the reference.

In contrast to Clark, Hess discloses that "[t]he array can also be loaded by applying a pressure across the platen, thereby causing a dilute solution of reagent and/or sample to flow through the array of through-holes". *See* col. 28, lines 16-19 (underlining added). This disclosure does not relate to the use of a syringe, and relates to the application of pressure across the platen. In addition, Hess does not disclose that there are problems with bubble formation when pressure is applied across the platen.

In this regard, the Examiner takes the position that the absence of such disclosure does not mean that there are no problems of bubble formation. However, without any teaching of a problem associated with pressure loading, the Examiner has not provided a basis or explanation for why one of ordinary skill in the art would modify the process of Hess.

For at least the above reasons, one of ordinary skill in the art would not look to Clark to modify Hess, particularly since Hess does not disclose any problems of bubble formation caused by pressure loading and Clark specifically addresses problems of bubble formation in a syringe.

Furthermore, there is no reasonable expectation of success. The Examiner asserts that while Hess does not explicitly describe bubble formation, it does not follow that Hess' system would not have problems with bubbles and that Clark's bubble-removal process would not work with Hess' system,

However, Hess discloses applying pressure across a platen and not to the use of a syringe. The Examiner fails to explain why or how Clark's bubble-removal process would work in Hess' system. Specifically, Clark discloses, at column 21, lines 32-48, that:

> While the crossflow is occurring, the piston 124 is reciprocated inside the bore 128. This reciprocation causes high fluid flow velocities in the annulus 138 between the piston 124 and the bore 128. The high flow velocity dislodges any bubbles that may be adhering to the piston 124 or bore wall. The inward stroke of the piston 124 pushes these dislodged bubbles across the crossflow area where they are swept out of the syringe. The piston end 132 and the bore end 130 have similar spherical shapes. When the piston 124 strokes to its full inward extension, it comes very close to the bore end 130. Any bubble that may be stuck on the bore end 130 is disrupted and dislodged. Likewise, when the piston strokes to its full outward extension, its end is flush with the seal 126. The sequence of reciprocating the piston while crossflowing can be automatically executed any time by the system.

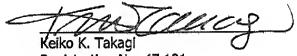
In the above disclosure, Clark discloses specific elements of the syringe and how it functions to remove the bubbles formed inside the syringe. It is submitted that the structural parts of the

syringe that remove the bubbles could not be incorporated into the pressure loading system of Hess. Therefore, contrary to the Examiner's position, one of ordinary skill in the art would not expect that Clark's bubble-removal step could be used in the pressure-loading system of Hess.

For the above reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established because there is no teaching or suggestion in either reference that would motivate one of ordinary skill in the art to modify the process of Hess based on Clark with a reasonable expectation of success to arrive at the claimed invention.

In view of the above, Appellants respectfully request the Pre-Appeal Brief Conference Panel to withdraw the foregoing rejection.

Respectfully submitted,



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